FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
Ohm Laboratories Inc.

Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 60 mg/120 mg

Drug Facts

Active ingredients (in each extended-release tablet)	*Purpose*
Fexofenadine HCl, USP 60 mg	Antihistamine
Pseudoephedrine HCl, USP 120 mg	Nasal Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have difficulty swallowing

Ask a doctor before use if you have

- heart disease
- thyroid disease
- glaucoma
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- kidney disease. Your doctor should determine if you need a different dose.

When using this product

- **do not take more than directed**
- do not take at the same time as aluminum or magnesium antacids

- do not take with fruit juices (see Directions)

Stop use and ask a doctor if
- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1800-222-1222).

Directions
- do not divide, crush, chew or dissolve the tablet; swallow tablet whole

adults and children 12 years of age and over	take 1 tablet with a glass of water every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours
children under 12 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information
- do not use if carton is opened or if individual blister units are torn or opened
- store between 20° to 25°C (68° to 77°F)
- USP dissolution test is pending.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

Questions or comments?

Call toll-free **1-800-818-4555 weekdays**

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 20 Tablet Blister Pack Carton

†Compare To
the active ingredients of
Allegra-D®

NDC 51660-037-21

ohm®

NON-DROWSY

Original Prescription Strength

Fexofenadine HCl 60 mg/Antihistamine
Pseudoephedrine HCl 120 mg/Nasal Decongestant
Extended-Release Tablets, USP

Allergy & Congestion

Indoor and Outdoor Allergies

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

12 Hour

Relief of:

- Nasal and Sinus Congestion Due to Colds or Allergies
- Sneezing; Runny Nose; Itchy, Watery Eyes and Itchy Nose or Throat Due to Allergies

20 Extended-Release Tablets

FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE

HYDROCHLORIDE

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-037
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	WHITE, YELLOW	**Score**	no score
Shape	CAPSULE (bilayer)	**Size**	17mm
Flavor		**Imprint Code**	724
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51660-037-21	1 in 1 CARTON	03/01/2018	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-037-31	1 in 1 CARTON	03/01/2018	
2		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090818	03/01/2018	

Labeler - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(51660-037) , MANUFACTURE(51660-037)

Revised: 5/2019 Ohm Laboratories Inc.